PCT/JP2003/013921

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
C1-A0229Y1P		
International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/JP2003/013921	30 October 2003 (30.10.2003)	30 October 2002 (30.10.2002)

International Patent Classification (IPC) or national classification and IPC

C12N 15/12, 1/15, 1/19, 1/21, 5/00, C07K 14/705, 16/28, C12P 21/02, G01N 33/15, 33/50, A61K 39/395, A61P 37/08

Applicant

CHUGAI SEIYAKU KABUSHIKI KAISHA

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 October 2003 (30.10.2003)	21 May 2004 (21.05.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/013921

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP03/13921

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☒ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

A matter common to the subject matters of claims 1-11 is considered to be (1) a DNA consisting of the base sequence represented by SEQ ID NO: 1 or 3 of the present application and encoding a mouse-derived membrane protein that has one immunoglobulin domain as an extracellular domain and has a motif for intracellular signal transfer, and (2) matters relating to it.

However, Biochem. Biophys. Res. Commun. {2001, 287 (1), pages 35-41} describes a mouse-derived DNA substantially identical with the DNA consisting of the base sequence represented by SEQ ID NO: 3 of the present application and encoding a mouse-derived membrane protein that has one immunoglobulin domain as an extracellular domain and has a motif for intracellular signal transfer. So, the above-mentioned common matter was considered to be not novel.

That is, since the said common matter belongs to the prior art, it is not a special technical feature in the sense of the second sentence of PCT Rule 13.2.

Therefore, there is no matter common to all the claims. Since there does not exist any other common matter considered to be a special technical feature in the sense of the second sentence of PCT Rule 13.2, no technical relationship in the sense of PCT Rule 13 can be found among the different inventions.

So, it is evident that claims 1-11 do not satisfy the requirement of unity of invention.

Therefore, the claims describe the following two inventions.

(1) A portion concerning the DNA consisting of the base sequence represented by SEQ ID NO: 1 of the present application, among the subject matters of claims 1-11

(2) A portion concerning the DNA consisting of the base sequence represented by SEQ ID NO: 3 of the present application, among the subject matters of claims 1-11

The scope that the International Preliminary Examining Authority thinks satisfies the requirement of unity of invention is as follows.

The portion concerning the DNA consisting of the base sequence represented by SEQ ID NO: 1 of the present application, among the subject matters of claims 1-11

The portion of the international application that the International Preliminary Examining Authority thinks relates to a major invention is as follows.

The portion concerning the DNA consisting of the base sequence represented by SEQ ID NO: 1 of the present application, among the subject matters of claims 1-11

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. _____.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP03/13921

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	9-11	YES
	Claims	1-8	NO
Inventive step (IS)	Claims	11	YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

2. Citations and explanations

Document 1: Biochem. Biophys. Res. Commun., 2001, 287 (1), pages 35-41
Document 2: Nucleic Acids Res., 2001, 29 (24), pages 4983-4993
Document 3: J. Exp. Med., 2000, 192 (7), pages 1059-1068
Document 4: Eur. J. Immunol., 2000, 30 (8), pages 2147-2156
Document 5: Immunol. Today, 2000, 21 (12), pages 611-614
Document 6 (Additional): J. Immunol., 1997, 159 (5), pages 2075-2077

The subject matters of claims 1-8 do not appear to be novel in view of document 1 cited in the ISR.
Document 1 describes (1) substantially the same DNA as the DNA consisting of the base sequence represented by SEQ ID NO: 3 of the present application, (2) an estimated amino acid sequence of protein DIgR1 encoded by the said DNA, (3) a vector having the said DNA inserted, (4) a host cell holding the said vector, (5) a method for producing the said DIgR1 by culturing the said host cell, and (6) an antibody against the said DIgR1.

The subject matter of claim 9 does not appear to involve an inventive step in view of document 1.
Screening the compounds capable of being bound to a certain protein was a well-known technique when the present application was filed.

The subject matter of claim 1 does not appear to be novel in view of document 2 cited in the ISR.
Document 2 describes a DNA about 60% homologous to the DNA consisting of the base sequence represented by SEQ ID NO: 1 of the present application (especially see GenBank Accession No. BG803833). The subject matter of claim 1 of the present application is a DNA capable of hybridizing with the DNA consisting of the base sequence represented by SEQ ID NO: 1 under a stringent condition, and the specification of the present application describes, "As a hybridization condition, for example, a less stringent condition can be enumerated" (page 8). Considering these, the DNA described in document 2 corresponds to the DNA of claim 1 of the present application.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Matters covered by the statement:

The "compounds" described in claim 11 are specified in such a manner that they "are obtained by the method described in claim 9 or 10," and include all the compounds obtained by the method (screening method) described in claim 9 or 10.

However, the specification does not describe any particular compound obtained by the said screening method. So, the subject matter of claim 11 is not supported by the specification and is not disclosed in the specification. Furthermore, even considering the common general technical knowledge prevailing on the filing date of the present application, it is quite unknown what compounds are included and what compounds are not included. So, the description of claim 11 is very unclear.

Therefore, among the subject matter described in claim 11, no significant statement can be presented concerning the portion relating to the compounds obtained by the method described in claim 9 or 10.

So, among the subject matter described in claim 11, the statement is made only on the portion relating to the antibody described in claim 7.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : V.2

The subject matters of claims 3-9 do not appear to involve an inventive step in view of document 2 cited in the ISR.

It was a well-known technique when the present application was filed that (1) a vector containing a DNA encoding a certain protein is used to transform a host cell, (2) the said host cell is cultured to produce the said protein, (3) an antibody against a certain protein is produced, and (4) the compounds capable of being bound to a certain proteins are screened.

The subject matter of claim 10 does not appear to involve an inventive step in view of documents 1 and 3-5 cited in the ISR.

Document 1 describes that DIgR1 is a noninhibitory molecule not having ITIM in an intracellular domain.

Documents 3-5 respectively describe that a noninhibitory/activatory molecule not having ITIM in an intracellular domain is bound to DAP12, DAP10 or FcRγ.

Furthermore, with regard to the two proteins having the affinity of being bound to each other, it was a well-known technique to screen the compounds capable of inhibiting the said binding, when the present application was filed.

So, a person skilled in the art could have easily conceived of (1) examining the affinity of DIgR1 described in document 1 of being bound to DAP12, DAP10 or FcRγ, and (2) screening the compounds capable of inhibiting the said binding with regard to the combinations of substances having the affinity of being bound to each other.

The subject matters of claims 1-9 do not appear to involve an inventive step in view of document 1 and newly cited document 6.

Document 6 describes that an inhibitory cell surface receptor belonging to the ITIM-bearing receptor family, and the noninhibitory/activatory counterpart of the said receptor not having ITIM in an intracellular domain, are highly homologous to each other in an extracellular domain.

So, a person skilled in the art could have easily conceived of (1) screening a mouse-derived cDNA library using the gene encoding the extracellular domain of DIgR1 described in document 1 as a probe, to obtain a DNA having ITIM in an intracellular domain and encoding the counterpart of DIgR1, (2) using a vector containing the said DNA for transforming a host cell, and (3) culturing the said host cell, to obtain the said counterpart.

Furthermore, when the present application was filed, producing an antibody against a certain protein, and screening the compounds capable of being bound to a certain protein were well-known techniques.

The subject matter of claim 10 does not appear to involve an inventive step in view of documents 1 and 4-6.

Documents 4-6 describe that an inhibitory molecule having ITIM in an intracellular domain is bound to SHP-1, SHP-2 or SHIP.

So, a person skilled in the art could have easily conceived of (1) screening a mouse-derived cDNA library using the gene encoding the extracellular domain of DIgR1 described in document 1 as a probe, to obtain a DNA having ITIM in an intracellular domain and encoding the counterpart of DIgR1, (2) using a vector containing the said DNA for transforming a host cell, (3) examining the binding affinity between the protein obtained by culturing the said host cell and SHP-1, SHP-2 or SHIP, and (4) screening the compounds capable of inhibiting the said binding with regard to the combinations of substances having the affinity of being bound to each other.

The subject matter of claim 11 appears to involve an inventive step in view of documents 1-6.

Documents 1-6 do not describe that an antibody against the protein of the invention of the present application can be used as an anti-allergic drug. A person skilled in the art could not have easily conceived of the constitution from the descriptions of documents 1-6.